

2024 Advocacy Accomplishments: Executive Summary

ADVOCACY WITH IMPACT

Issue. Action. Impact.



Providing a Collaborative, Unified Voice to Impact Wound Care Regulatory and Legislative Policies

Executive Summary: 2024 Advocacy Highlights



- ✓ **Enabled wound care providers using CTPs to have application flexibility, an extended episode of care, and an expanded timeframe to implement the final CTP local coverage determinations** published in November by successfully advocating the Medicare Administrative Contractors to remove arbitrary application limitations and incorporate substantive stakeholder input in the final policies. The final policies included considerable improvements to the clinical practice limitations included in the proposed policies issued in April 2024 and now better protect quality patient care and evidence-based treatment.
- ✓ **Successfully encouraged CMS to establish a national payment rate for blood-derived products** in chronic diabetic wounds to better reflect the complexity, time, and costs associated with these products, then persuaded the Agency to increase the initially proposed rate in the draft policy to a higher rate in the final rule. These products are now no longer contractor priced and, as a result of Alliance advocacy, have a national, consistent payment rate that gives clinicians predictable reimbursement when treating patients.
- ✓ **Gained key “fixes” to surgical dressings claims processing issues that were impacting access.** Identified issues, compiled examples and educated DMEMAC medical directors about issues, mobilizing them to review and adjust claims processing system to fix inconsistent surgical dressings claim denials and make updates to address maximum allowed surgical dressing quantities per patient/per month with multiple wounds.
- ✓ **Achieved update to DMEMAC surgical dressings policy article** that was causing systematic denials and challenging access for patients with multiple wounds. Drafted by the Alliance and forwarded to the DMEMACs for consideration, the language published in the February 2024 policy article update clarifies surgical dressing modifier quantity limitations, facilitating coverage and payment for surgical dressing application to a second wound.
- ✓ **Led advocacy urging FDA to withdraw its proposal to reclassify hundreds of antimicrobial wound products** to class III, a policy shift that would result in the unnecessary removal of many important products from the market and challenge quality care. Convened meetings with FDA and submitted comments - along with many other organizations and practitioners - emphasizing the unintended impact of this proposed classification change.
- ✓ **Successfully escalated concerns with the episode-based cost measure being developed for non-pressure ulcers** via a series of letters, comments and conversations flagging flaws in the field testing and the many ways the measure did not accurately capture the data necessary for a fair, reliable measure. Following tenacious Alliance advocacy, CMS' Pre-Rulemaking Measure Review Clinician Recommendation Group did not reach consensus regarding the measure at its January 2025 meeting. As a result, the measure will not be considered for adoption until further work and testing is undertaken.
- ✓ **Urged CMS to enable payment for clinicians to measure and fit lymphedema compression garments** via an ongoing advocacy initiative of letters, comments and meetings to keep focus on this issue.
- ✓ **Gained HOPPS Panel support of the Alliance’s recommendation to fix flawed total contact casting payment** with a separately payable APC code for TCC when performed on the same date of service as a debridement and/or the application of CTP. This would remove a barrier that inconveniences patients and providers by preventing these treatments from being performed on the same date.
- ✓ **Pursued update to DMEMAC LCD to establish coverage of topical oxygen therapy** for diabetic foot ulcer.
- ✓ **Proactively advanced CTP payment methodology recommendations focused on ASP pricing** as CMS continues to consider and vet its payment approach to these products across sites of care.
- ✓ **Maintained focus on the important role of real-world evidence in wound care research** and the importance of FDA/CMS dialogue to move forward.
- ✓ **Submitted 32 comments to regulators and legislators,** elevating the visibility, voice and influence of the wound care community in policy development.

A Message from our Executive Leadership



Dr. Matthew Garoufalis
Board Chair



Kara Couch
Board Vice Chair



Marcia Nusgart
CEO

Issue. Action. Impact.

These are words that guide our wound care advocacy work. Effective advocacy requires a deep and nuanced understanding of policy issues together with strategic, focused collaborative action to have impact. Our laser-focused advocacy requires persistence, patience and proactivity, and determination. Indeed, it takes downright doggedness to be the “wound care policy watch dog” protecting and defending wound care for the past 20+ years. Importantly, our tenaciousness pays off. Our impact in 2024 was extensive, with advocacy accomplishments that demonstrate the depth of our relationships with government agencies, the influence of collaborative action and a unified voice in shaping policies that protect and support quality wound care.

Wound care organizations and providers thrive when government regulations support fair reimbursement, appropriate coverage, and equitable patient access.

That is our focus.

Advocacy Success

Cellular and Tissue-based Products for Wounds (CTPs)

We protected quality clinical care.

Years of advocacy addressing local coverage determinations (LCDs) for CTP resulted in final policies issued in November 2024 that reflect substantive stakeholder input and remove arbitrary application limitations that had been included in prior drafts. The final LCD guiding use of CTPs in diabetic foot ulcers and venous leg ulcers now enable clinicians to have application flexibility and an extended episode of care to help heal the chronic wounds of their patients. The improvements made to the policy on the clinical care front illustrate the power of a unified voice to impact change. Importantly, our tenacious engagement in this area won't stop now that final versions have published. We immediately elevated concerns to CMS and the MACs and have put pressure on the Agency to more clearly specify the process and timeline by which new evidence can be submitted and reviewed for coverage, and to expand the number of covered products available for use treating DFU/VLU.

Advocacy Success

Blood-Derived Products

We attained reimbursement that better reflects the true cost of delivering care.

Advocacy to multiple MAC medical directors and CMS division heads resulted in the establishment of a national Medicare reimbursement rate for blood-derived products for use treating chronic diabetic wounds. Now set in the 2025 Medicare Physician Fee Schedule, the national rate replaces the inconsistent, inequitable contractor rates that caused access challenges in the physician office setting - as providers lost money when using autologous blood derived products to treat their patients. As a result of Alliance advocacy outreach and education, CMS not only established a national payment rate better reflecting the complexity, time, and costs associated with these products, but then increased the initially proposed rate to a higher rate in the final rule as a direct result of Alliance efforts.

**Advocacy
Success**
Surgical Dressings

We fixed claims processing issues that were driving denials and impacting access.

When members of the Alliance’s surgical dressings workgroup identified shared claim processing issues and compiled specific examples of inconsistent/inaccurate denials related to the maximum allowed quantities per patient/per month with multiple wounds, the Alliance alerted the DMEMAC medical directors. Our collection of denied claims provided impetus to the DMEMACs to review and adjust their claims processing to fix the issue that was resulting in denials. An additional outcome: the DMEMACs updated their surgical dressings policy article with language suggested by the Alliance to clarify modifier quantity limitations facilitating coverage and payment for surgical dressing application to a second wound.

These successes are a testament to the strength, power, and influence of having our collaborative work and unified voice, and they are just some of the many impressive advocacy initiatives detailed in this year’s annual report. As you’ll read, in 2024 we developed and submitted 32 comments, letters and oral testimonies to regulators and legislators, spanning a broad number of policies that impact wound care.

2024 Submitted Comments Weighing in with a United Voice on Policies Impacting Wound Care

26 to CMS & CMS Contractors	3 to FDA	2 to Congress	1 to Private Payer
Policies addressed: →			
<ul style="list-style-type: none"> Physician Fee Schedule Hospital Outpatient PPS Home Health PPS LCD on CTPs in DFU/VLU LCD on Non-Invasive Vascular Studies Non-Pressure Ulcers Episode-Based Cost Measure CAC Engagement CAC Review of Topical Oxygen Therapy MAC Consolidation 	<ul style="list-style-type: none"> Proposed New Classification of Antimicrobial Wound Dressings Guidance on Real-World Evidence for Medical Devices Tissue Reference Group Letters 	<ul style="list-style-type: none"> 21st Century Cures Act CTP Coverage & Payment 	<ul style="list-style-type: none"> Intravascular Ultrasound Policy Revision

Together, we make wound care better.

We’re excited to share a detailed overview of our 2024 Alliance advocacy through this “Issue – Action - Impact” framework. We also want to recognize that the work we are doing and impact we are having is only possible because of the dedication and ongoing work of our staff, Board, and member representatives. Thank you for your collaboration and support. It is our active, engaged members that enable our impressive breadth of advocacy initiatives. We make wound care better and more accessible to patients and providers nationwide.

We can’t do it without you, and as always, we are stronger together!

- Matthew Garoufalidis, DPM, FASPS, FACFAOM, CWS** - Board Chair
- Kara Couch, MS, CRNP, CWCN-AP, FAWC** - Board Vice Chair
- Marcia Nusgart, R.Ph.** - CEO

